UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
DOCKET NO. 1:17-cv-00031-MOC-DCK

KRISTIANA TWEED BURRELL,	)	
	)	
Plaintiff,	)	
	)	
v.	)	ORDER
	)	
BAYER CORPORATION	)	
BAYER HEALTHCARE LLC	)	
BAYER HEALTHCARE PHARMACEUTICALS, INC.	)	
BAYER ESSURE, INC.	)	
CHRISTOPHER FORD WILLIAMS	)	
BILTMORE OB-GYN, P.A.	)	
STACY D TRAVIS,	)	
	)	
Defendants.	)	

THIS MATTER is before the court on the pending Motion to Dismiss (#11) in this matter as well as the plaintiff's Motion to Reconsider or Alternatively Certify for Appeal (#33).[1] Having considered the Motion and reviewed the pleadings, the court enters the following Order.

FINDINGS AND CONCLUSIONS

I. Background

This is a case regarding the birth control medical device, Essure. The device was inserted into the plaintiff, and soon thereafter problems arose, which precipitated this suit.[2]

[1] The court acknowledges that defendants Travis and Biltmore OB-GYN, P.A. filed a Motion to Dismiss for failure to state a claim (#26), but it is not yet ripe for judicial review.
[2] Plaintiff's husband also filed suit with a nearly identical Complaint. His suit has been consolidated into this lead case by prior Order (#36) of this court.

Essure is a Class III medical device regulated by the Food and Drug Administration (FDA), and it is manufactured and marketed collectively by the Bayer defendants ("Bayer" or "Bayer defendants").[3] The FDA's authority over such medical devices derives from the Federal Food, Drug, and Cosmetic Act (FDCA) as amended by the Medical Device Amendments (MDA) of 1976, *et seq.* The MDA included a statutory framework highly relevant to the instant case.

Under the MDA, Class III medical devices are subject to FDA pre-market approval as to the "reasonable assurance" of their safety and effectiveness. See 21 U.S.C.A. § 360c(a)(1)(C). Pursuant to the MDA, Essure was granted pre-market approval by the FDA in 2002. The MDA also includes an express preemption clause, 21 U.S.C. § 360k, which contains the following general rule:

> **(a) General rule.** Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> **1.** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **2.** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter

21 U.S.C. § 306k(a).[4]

Following the problems encountered by the plaintiff, suit was filed in North Carolina state court in December 2016. *Inter alia*, the plaintiff's Complaint (#1-1, #1-2) asserts the following causes of action: (1) negligence, (2) products liability, (3) breach of express warranty, (4) breach of implied warranty, (5) fraud, (6) unfair or deceptive trade practices, and (7) medical

[3] The remaining defendants include Dr. Travis, the physician who performed the operation, and Biltmore OB-GYN.

[4] Plaintiff's Response (#20) acknowledges the express preemption clause of the MDA and quotes therefrom. (#20) at 3.

malpractice against defendant Travis and Biltmore OB-GYN. Complaint (#1-2). The case was removed by defendants in January 2017.

Subsequent to removal, the Burrell family (then in two separate cases) filed a Motion to Remand (#16). The cases were consolidated for pre-trial matters, *see* Order (#36), and the Motion to Remand was denied. (#31). The plaintiff now asks the court to reconsider its prior Order regarding remand under Rule 59.

Defendants have filed Motions to Dismiss. The Motion to Dismiss (#11) filed by the Bayer defendants is ripe for review and fully briefed. After reviewing the applicable standards under Rules 12(b)(6) and 59, the court will examine the arguments regarding the pending Motion.

II. 12(b)(6) Standard

In determining whether a claim can survive a motion under Rule 12(b)(6), the Supreme Court held in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007) that the "no set of facts" standard only describes the "breadth of opportunity to prove what an adequate complaint claims, not the minimum adequate pleading to govern a complaint's survival." Id. at 563. The Court specifically rejected use of the "no set of facts" standard because such standard would improperly allow a "wholly conclusory statement of claim" to "survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some 'set of [undisclosed] facts' to support recovery." Id. at 561 (alteration in original).

Post Twombly, to survive a Rule 12(b)(6) motion to dismiss, a claimant must allege facts in his complaint that "raise a right to relief above the speculative level." Id., at 555.

> [A] plaintiff's obligation to provide the "grounds" of his "entitle[ment] to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do ....

Id. (second alteration in original; citation omitted). Further, a complaint will not survive Rule 12(b)(6) review where it contains "naked assertion[s] devoid of further factual enhancement." Id., at 557. Instead, a claimant must plead sufficient facts to state a claim for relief that is "*plausible* on its face." Id. at 570 (emphasis added).

Subsequent to Twombly, the Court revisited the Rule 12(b)(6) pleading standard in Ashcroft v. Iqbal, 556 U.S. 662 (2009). In Iqbal, the Court determined that Rule 8 "demands more than an unadorned, the defendant-unlawfully-harmed-me accusation." Id. at 678. The Court explained that, "to survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is *plausible* on its face.'" Id. (citing Twombly, supra) (emphasis added). What is plausible is defined by the Court:

> [a] claim has facial plausibility when the plaintiff pleads sufficient factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

Id. This "plausibility standard" requires "more than a sheer possibility that a defendant has acted unlawfully." Id. Thus, a complaint falls short of the plausibility standard where a plaintiff pleads "facts that are 'merely consistent with' a defendant's liability...." Id. While the court accepts plausible factual allegations made in a claim as true and considers those facts in the light most favorable to plaintiff in ruling on a motion to dismiss, a court "need not accept as true unwarranted inferences, unreasonable conclusions, or arguments." Eastern Shore Mkts. Inc. v. J.D. Assoc.'s, LLP, 213 F. 3d 175, 180 (4th Cir. 2000).

In sum, when ruling on a Rule 12(b)(6) motion, "a judge must accept as true all of the factual allegations contained in the complaint." Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam) (citations omitted). A complaint "need only give the defendant fair notice of what the claim is and the grounds upon which it rests." Id. at 93 (alteration and internal quotation marks omitted). However, to survive a motion to dismiss, the complaint must "state [ ] a plausible claim for relief" that "permit[s] the court to infer more than the mere possibility of misconduct" based upon "its judicial experience and common sense." Iqbal, 129 S. Ct. at 1950. A plaintiff need not, however, demonstrate that his right to relief is probable or that alternative explanations are less likely; rather, he must merely advance his claim "across the line from conceivable to plausible." Twombly, 550 U.S. at 570. If his explanation is plausible, his complaint survives a motion to dismiss under Rule 12(b)(6), regardless of whether there is a more plausible alternative explanation

III. Reconsideration Standard

Regarding Motions for Reconsideration, Fed. R. Civ. P. 54(b) provides, in relevant part:

> any order or other decision, however designated, that adjudicates fewer than all the claims … may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Id. Courts have an inherent authority to reconsider and revise any interlocutory order. See Beyond Sys., Inc. v. Kraft Foods, Inc., No. CIV.A. PJM-08-409, 2010 WL 3059344, at *1 (D. Md. Aug. 4, 2010) ("reconsideration of an interlocutory order is within the plenary powers of the Court and can be made 'as justice requires.'") (quoting 7 James Wm. Moore et al., Moore's Federal Practice ¶ 60.20 (2d ed.1966)). The exact standard governing Motions to Reconsider orders other than final judgments under Rule 54 is not set in stone, but the Fourth Circuit has

stated that Rule 54(b) motions are "not subject to the strict standards applicable to motions for reconsideration of a final judgment." Am. Canoe Ass'n v. Murphy Farms, Inc., 326 F.3d 505, 514 (4th Cir.2003). That is because "a district court retains the power to reconsider and modify its interlocutory judgments, including partial summary judgments, at any time prior to final judgment when such is warranted." Id. Mindful of such instructions, "district courts in the Fourth Circuit generally look to Rule 59(e)'s standards for guidance." Regan v. City of Charleston, S.C., 40 F. Supp. 3d 698, 701–02 (D.S.C. 2014) (citing Joe Hand Promotions, Inc. v. Double Down Entm't, LLC, No. 0:11-CV-02438, 2012 WL 6210334, at *2 (D.S.C. Dec. 13, 2012); Ruffin v. Entm't of E. Panhandle, 3:11–CV–19, 2012 WL 1435674, at *3 (N.D.W.Va. Apr. 25, 2012)). Under that standard, the Fourth Circuit has recognized "three grounds for amending an earlier judgment: (1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." Pac. Ins. Co. v. Am. Nat'l Fire Ins. Co., 148 F.3d 396, 403 (4th Cir. 1998) (citing EEOC v. Lockheed Martin Corp., 116 F.3d 110, 112 (4th Cir. 1997). Rule 59(e) provides an "extraordinary remedy that should be used sparingly," id. (internal citation omitted), which is ultimately within "the sound discretion of the district court." Singletary v. Beazley Ins. Co., 2013 WL 6850147, at *2 (D.S.C. Dec. 30, 2013) (citation omitted). Importantly, Rule 59(e) motions "may not be used to relitigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgment." Pac. Ins. Co., 148 F.3d at 403 (citation and internal quotations omitted). Likewise, a Rule 59(e) motion is not an opportunity to relitigate issues already ruled on because a litigant is displeased with the result. United States ex rel. Becker v. Westinghouse Savannah River Co., 305 F.3d 284, 290 (4th Cir. 2002).

Here, plaintiff has provided the court with no reason under the governing standards to modify its prior ruling. Plaintiff cites to the Fourth Circuit's decision in Pinney v. Nokia, Inc., which noted in part:

> "a preemption defense that raises a federal question is inadequate to confer federal jurisdiction. Again, a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption," even if the complaint begs the assertion of the defense, and even if the defense is the only question truly at issue in the case."

402 F.3d 430, 446 (4th Cir. 2005) (citations and quotations omitted). The court distinguishes the instant case from Pinney. Notably, in Pinney, federal law was "lurking" as a question in the background, as state law claims made no reference to federal law. *Id.* By plaintiff's own admission here, plaintiff alleges violations of the FDCA as part of the state law claims. As noted in the court's prior Order denying remand (#31), this case meets the requisite four-part test under Gunn v. Minton, 133 S. Ct. 1059, 1065 (2013) for federal jurisdiction. As the Supreme Court noted in Gunn, jurisdiction would be proper as there is "serious federal interest in claiming the advantages thought to be inherent in a federal forum," which can be vindicated without upsetting the balance of labor between the federal and state courts.

Plaintiff has largely reasserted the same reasons articulated in the prior Motion for Remand (#16) and now hopes for a different result. As such, the Motion for Reconsideration (#33) will be denied. The alternative Motion for Certification to Appeal (#33) is also denied for reasons discussed further below.

IV. Preemption

Federal law generally recognizes a presumption against preemption, but notes that a federal statute can preempt state law when Congress' intent to do so was "clear and manifest." Wyeth v. Levine, 555 U.S. 555, 565 (2009). With regard to pre-market approved Class III medical devices like Essure, the applicable federal statute, 21 U.S.C. § 360k, contains an express preemption clause, noted above. This express preemption clause makes Congressional intent both clear and manifest: state laws that impose obligations "different from or in addition to" the requirements of the MDA are expressly preempted. See 21 U.S.C. § 360k; Riegel v. Medtronic, Inc. 552 U.S. 312, 321 (2008). In addition to express preemption, the Supreme Court has also held that state law claims are impliedly preempted under the FDCA, if the state law violation was solely based on a violation of the FDCA. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001).

Accordingly, the task of avoiding express and implied preemption is a difficult one, as "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)." In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (citation and internal quotations omitted). Plaintiff must assert state law claims that are totally parallel to the federal law and not derivative thereof, which fall into a "narrow gap." Id. The difficulty in achieving claims that fall into this narrow gap to avoid federal preemption has been compared to "the task of navigating between Scylla and Charybdis." See Caplinger v. Medtronic, Inc., 784 F.3d 1334, 1340 (10th Cir. 2015); see also Norman v. Bayer Corp., No. 3:16-CV-00253, 2016 WL 4007547, at *2 (D. Conn. July 26, 2016).

The Bayer defendants claim that each of the plaintiff's causes of actions are preempted. (#12) at 9. Plaintiff reminds the court that preemption does not "afford indiscriminate immunity from liability for violations of state law that parallel federal regulations" and asks that the court deny the Motion to Dismiss in its entirety. (#19) at 1. The numerous causes of actions will be reviewed below on preemption grounds.

V. Discussion

Plaintiff argues in her Complaint (#1-1) that her claims are brought under parallel state law and do not implicate federal law. (#1-1) at ¶ 22. The primary issue before the court is whether the state law claims raised in the plaintiff's complaint are preempted under federal law. A secondary issue, raised by plaintiff's claims of fraud and violations of N.C. Gen. Stat. §75-1.1 *et seq*., the state's unfair trade practices act, will also be addressed below. The court will also review the medical malpractice claim that arises solely from state law, rather than the FDCA.

i. Negligence

Plaintiffs allege negligence based largely on a failure-to-warn theory, including allegations that the Bayer defendants failed to warn of adverse events related to Essure. See Complaint (#1-2) at ¶ 168-181. The Complaint (#1-2) speaks largely of failure-to-warn negligence and failure to take reasonable care in the manufacture of the product. Id. at 168-181.

According to plaintiff, the Bayer defendants "were under a continuing duty to comply with the requirements listed [in the pre-market approval] and with the FDCA in the manufacture, development, promotion, marketing, labeling, distribution, and sale of Essure." Id. at ¶ 195. The court agrees and notes that the source of this continuing duty was federal law: the FDCA, as amended by the MDA. Under Buckman, the plaintiff cannot use a private suit to enable private

party enforcement of the MDA. See In re Medtronic, 623 F.3d at 1205-06. A requirement to report adverse events exists under the FDCA, and plaintiff's cause of action is being brought because the Bayer defendants allegedly failed to meet these reporting requirements. See Buckman, 531 U.S. at 353; Norman, 2016 WL 4007547 at *4. Accordingly, the plaintiff's failure-to-warn claim is preempted.

Even if the court was to examine the issue of negligence under state law, plaintiff cannot support a finding of causation, required for a finding of negligence. Plaintiff alleges that the Bayer defendants did not adequately provide warnings of adverse events to the FDA. See Complaint (#1-1) at ¶¶ 90-91, 63-65, 75-81. In particular, plaintiff alleges that "physicians would never recommended, and plaintiff would never had Essure implanted, had they been aware" of over 16,000 complaints "or the falsity of representations" otherwise mentioned. Complaint (#1-2) at ¶ 195. It is undisputed that plaintiff had the Essure device inserted in December 2013. By that time, the FDA had the related information regarding the adverse event reports mentioned by plaintiff, as FDA investigations had found the adverse events to that date. Accordingly, she has failed to show that the failure-to-warn caused her injuries as the FDA became aware of the adverse events months before as she has failed to provide a sufficient causal link between the failure to warn and the alleged injury. See De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1097 (N.D. Cal. 2016). Indeed, the newly-implemented black box warning, as described in the Complaint (#1-1) at ¶¶ 132-140, is a new *type* of warning, but does not provide *new* information not otherwise noted; the same information was available on the prior labeling. See Norman, 2016 WL 4007547 at *4.

To the extent that plaintiff cites to California law to support her conclusions, Complaint (#1-2) at ¶ 199, such authority is noted but is inapplicable here. The court would apply North Carolina law, and California law has little connection to the case at bar.

In addition, the plaintiff alleges that the Bayer defendants failed to properly train Dr. Travis to implant the device, deal with potential complications, and remove the device. Complaint (#1-1, #1-2) at ¶¶ 110, 121, 203, 204(f), & 204(g). This negligent training claim is preempted and otherwise fails. First, it is preempted as it imposes a duty that is beyond the confines of the MDA. Such a claim survives preemption only to the extent that the manufacturer failed to provide the training required by the MDA. Frere v. Medtronic, Inc., No. EDCV1502338BRODTBX, 2016 WL 1533524, at *10 (C.D. Cal. Apr. 6, 2016); De La Paz, 159 F. Supp. 3d at 1096. The Complaint does not provide information as to how the training violated the FDA's requirements or how her physician was trained. The court is left to guess as to how the actions of any defendant violate any FDA-mandated training. Second, plaintiff has not provided sufficient facts as to the plausibility of *how* any failure in training caused the plaintiff's injuries. See McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804, 817 (E.D. Pa. 2016); Norman, 2016 WL 4007547, at *5. To the extent that there may exist a negligent training claim in North Carolina, it is clear to the court that such a claim, as with any tort, must include a causal connection between the violation of a duty and the harm suffered. Norman, 2016 WL 4007547, at *5. As in Norman, such causation is lacking here. There is a conclusion in the Complaint (#1-2) that defendant Williams "failed to ensure that Dr. Travis performed the surgery properly," at ¶ 203, but there is little causal connection between the any training and the harm alleged. The

factual basis in the Complaint is insufficient to plausibly state a claim under Twombly and Iqbal, as it relies on conclusions rather than a sufficient factual basis and causal connection.

Plaintiff also alleges that the product was manufactured improperly. See id. at ¶¶ 205-211. To survive preemption, manufacturing defect claims must allege that the device was not made in accordance with the specifications approved by the FDA. See Norman, 2016 WL 4007457, at *3. Further, plaintiff has not linked any manufacturing deficiency to the device that the plaintiff received and how it caused the alleged injuries, which federal courts have found to be a necessary component of a negligent manufacturing defect claim. See, e.g. Bass v. Stryker Corp., 669 F.3d 501, 511–12 (5th Cir. 2012); Wolicki–Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301–02 (11th Cir.2001); McLaughlin, 172 F. Supp. 3d at 835–36. Even if there were non-conforming devices manufactured by the Bayer defendants, it is unclear whether the plaintiff received an item from a non-conforming batch or that it suffered from any other manufacturing defect. See Id.; De La Paz, 159 F.Supp. 3d at 1094.

The Complaint asserts that the Essure product "differed from the Bayer Defendants' intended result and design specifications." (#1-2) at ¶ 225. Plaintiff, relying on a case from an Indiana district court, argues that this assertion is sufficient to show that defendant failed to meet the FDA's manufacturing requirements and should be subject to civil suit. See Hofts v. Howmedica Osteonics Corp. 597 F.Supp.2d at 830, 836. However, under Twombly and Iqbal, there must be factual allegations that support inferences upon which the defendants' liability and plaintiff's right to relief rests; this allegation and the pleadings overall fail to provide adequate notice of the grounds for a manufacturing defect suit. See Ali v. Allergan USA, Inc., No. 1:12-CV-115 GBL/TRJ, 2012 WL 3692396, at *12 (E.D. Va. Aug. 23, 2012).

ii. Products Liability

Plaintiff further asserts a claim under a products liability theory. Complaint (#1-2) at ¶¶ 214-241. In large part, the plaintiff articulates a failure to warn theory. For example, plaintiff writes "Had the Bayer Defendants timely and adequately reported the adverse events to the FDA, there would have been effective warnings to physicians…" Complaint (#1-2) at ¶ 233. The failure to warn claims are again preempted under Buckman's implied preemption for the reasons discussed above.

Insofar as plaintiff argues that Essure suffered from a design defect, see, e.g. Complaint (#1-2) at ¶¶ 173, 204, 223, & 259, those are explicitly preempted. The MDA mandates that the FDA enforces the safety and effectiveness of regulated devices, particularly Class III pre-market approved medical devices. Put simply, the FDA made its determination of this products safety and effectiveness for its given use. As the plaintiff cannot allege that Bayer departed from its FDA-approved design of this product, these design defect claims are preempted. See De La Paz, 159 F. Supp3d at 1095.

If the court were to apply state law to the second claim of products liability, the court would need to apply N.C. Gen. Stat. § 99B-1.1. This short statute simply states, "There shall be no strict liability in tort in product liability actions." N.C. Gen. Stat. § 99B-1.1. To the extent that plaintiff's products liability claim posits a strict liability theory, state law does not recognize such a theory. See Am. & Efird LLC v. Pittsfield Plastics Eng'g, Inc., No. 3:12CV194, 2012 WL 5463130, at *1 (W.D.N.C. Nov. 8, 2012).

iii. Breach of Warranties: Express and Implied

Plaintiff argues that the Essure Class III medical device breached its express and implied warranties. With regard to express warranties, the plaintiff argues that the Bayer defendants "expressly warranted Essure to be safe for use by the general public, including Plaintiff and/or her healthcare providers." Complaint (#1-2) at ¶ 244. Plaintiff alleges that the Bayer defendants' warranties and representations "were untrue in that Essure was unsafe and unsuited for the use for which it was intended." Complaint (#1-2) at ¶ 244. Such claims are expressly preempted. Congress provided the FDA with the authority to regulate the safety and effectiveness of Class III medical devices, like Essure, under the MDA. The determination was the FDA's to make, and they provided pre-market approval for Essure, thereby noting its safety and effectiveness for its intended use. Accordingly, this cause of action is dismissed.

In arguing a breach of implied warranty, plaintiff alleges that at all relevant times, Essure was "not reasonably safe for its expected purpose." Complaint (#1-2) at ¶ 259. Such as claim is expressly foreclosed by preemption. The FDA, under the FDCA and the MDA, has the express authority to make such determinations as to the safety and effectiveness of Class III medical devices. This cause of action is expressly preempted and will be dismissed.

iv. Fraud and Unfair Trade Practices

Plaintiff's fifth and sixth causes of action relate to fraud and a state law claim under the state's unfair or deceptive trade practices act, N.C. Gen. Stat. § 75-1.1. These allegations largely repackage the allegations discussed above, asserting that the Bayer defendants fraudulently concealed information related to the risks of the Essure product and failed to warn the public and the FDA about these risks. See, e.g. Complaint (#1-1, #1-2) at ¶¶ 269, 277, 286 and 293. These claims are preempted and otherwise fail.

With regard to preemption, several of the alleged misrepresentations are indistinguishable from FDA-approved labeling statements. See, e.g. De La Paz, 159 F.Supp.3d at 1097-99; Norman, 2016 WL 4007437, at *3-*6. Federal regulations prohibit a device from being labeled or advertised in a manner inconsistent with the FDA's pre-market approval. See 21 C.F.R. 814.80. The *de minimis* deviations from the FDA-approved language do not support a claim based on fraudulent behavior or unfair trade practices. Accordingly, these claims are preempted.

As a separate and independent matter, the Federal Rules of Civil Procedure mandate particular pleading requirements. See F.R.C.P. Rule 9(b). In relevant part, the Federal Rules require that parties alleging fraud or mistake "state with particularity the circumstances constituting fraud or mistake." Id. Rule 9(b) requires those alleging fraud "must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." United States v. Triple Canopy, Inc., 775 F.3d 628, 634 (4th Cir.2015) (internal quotation omitted). As a general rule, "[a] court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999). In other words, plaintiffs must state the "who, what, when, where and how of the alleged fraud." Smith v. Clark/Smoot/Russell, 796 F.3d 424, 432 (4th Cir. 2015).

Plaintiff alleges that she and her physician relied on information provided by the Bayer defendants in making the determination to get the Essure device implanted, and she or her physician would not have had the surgery if the information had not been concealed or

misrepresentations had not been made. See Complaint (#1-2) at ¶¶ 274, 277, 291. Plaintiff further alleges that Bayer defendants and Mr. Williams made affirmative representations that Essure was "safe and effective." Complaint (#1-2) at ¶ 269. Specifically, plaintiff claims that she would "never have had the Essure device implanted had she been aware that there were multiple reports of perforations of human cavities or that there had been 16,04 complaints regarding Essure." Complaint (#1-2) at ¶ 274.

If the court were to assume arguendo that the pleading requirements of Rule 9(b) are met, the claims must also survive plausibility challenges under Twombly and Iqbal. The FDA, pursuant to the MDA, had made the determination of the safety and effectiveness of Essure. As noted above, the adverse event reports were provided to the FDA by the time the plaintiff had her surgery. With regard to the alleged misrepresentations, the claims were preempted. Accordingly, the claims will be dismissed.

i. Medical Malpractice

The plaintiff has also alleged a claim of medical malpractice against defendants Travis and Biltmore OB-GYN. See Complaint (#1-2) at ¶¶ 299-309. Notwithstanding the unripe Motion to Dismiss (#26) filed by these defendants, the claims are not preempted under federal law as the duties arise solely from state law. Put simply, alleging that the health care providers fell below a certain standard of care would be a failure to comply with applicable state law, not the FDCA. Even if this is the sole claim that survives the preemption analysis, the court may choose to exercise supplemental jurisdiction over it as it relates to the same core nucleus of operative fact as the other claims. See 28 U.S.C. § 1367.

To prevail on a medical malpractice claim in North Carolina, a plaintiff must establish: (1) the applicable standard of care; (2) the defendant's breach of that standard; and (3) that the breach caused the plaintiff's injury. Frazier v. Angel Med. Ctr., 308 F. Supp. 2d 671, 676 (W.D.N.C. 2004). The court notes that the state law requires special pleading requirements for such claims, which *inter alia* mandates that pleadings must assert that medical care and medical records related to the malpractice claim have been reviewed by a putative expert witness who is willing to testify that the medical care violates the applicable standard of care. N.C. R. Civ. Procedure 9(j). The court notes that plaintiff has objected to such pre-filing requirements but nonetheless appear to have complied with the pleading requirements. Complaint (#1-2) at ¶ 303. While plaintiff has argued that this pleading requirement is unconstitutional, the state supreme court has specifically upheld Rule 9(j). See Anderson v. Assimos, 356 N.C. 415 (2002). The parties are reminded that North Carolina is a contributory negligence state, and negligence on the part of the plaintiff occurring subsequent to the operation can significantly mitigate potential damages. See Andrews v. Carr, 521 S.E.2d 269, 273 (N.C. App. 1999) (discussing exercise and sexual intercourse following a surgical operation into plaintiff's penis occurring against physicians' advice).

As discussed above, the court has concluded that each of the plaintiff's claims—other than medical malpractice—are preempted by federal law and must be dismissed. Under 28 U.S.C. § 1367(c)(3), the court may decline to exercise supplemental jurisdiction when all claims over which the court has original jurisdiction have been dismissed. Such is the case here. Accordingly, the court will decline to exercise supplemental jurisdiction. The plaintiff is advised that 28 U.S.C. § 1367(d) may affect the period of limitations for this tort claim.

VI. Conclusion

Essure is a Class III medical device regulated by the FDA, pursuant to the MDA. In addition to the MDA's express preemption provision, federal courts have also found implied preemption pursuant to Buckman. This has resulted in a difficult "narrow gap" within which plaintiff's claim could succeed. Plaintiff's claims largely fall outside of this narrow gap and are preempted as a result.

Specifically, plaintiff has pled the following causes of action: (1) negligence, (2) products liability, (3) breach of express warranty, (4) breach of implied warranty, (5) fraud, (6) unfair or deceptive trade practices, and (7) medical malpractice against defendant Travis and Biltmore OB-GYN. Complaint (#1-2). Claims numbered one (1) through six (6) are hereby dismissed for the reasons explained above. As the claims are dismissed, there is no need to certify the issue of remand for appeal, as the Circuit may consider the dismissal and remand as one matter if the case is appealed. Accordingly, the alternative Motion to Certify the Issue for Appeal (#33) is also denied.

The one cause of action that is not preempted is the medical malpractice claim, which arises solely from state law, rather than the FDCA. The parties are reminded that North Carolina is a contributory negligence state for this tort claim. The court will not exercise supplemental jurisdiction over this medical malpractice claim under 28 U.S.C. § 1367(c)(3), as it has dismissed all claims over which it has original jurisdiction. Accordingly, that claim is also dismissed—as the court declines to exercise its supplemental jurisdiction—but the cause of action may be re-asserted in state court.

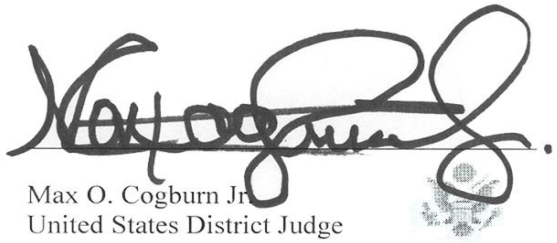
ORDER

IT IS, THEREFORE, ORDERED that the pending Motion to Dismiss (#11) is **GRANTED**. Claims related to (1) negligence, (2) products liability, (3) breach of express warranty, (4) breach of implied warranty, (5) fraud, and (6) unfair or deceptive trade practices are **DISMISSED**, with prejudice, as they are preempted under federal law.

The court declines to exercise its supplemental jurisdiction over the medical malpractice claim pursuant to 28 U.S.C. § 1367(c)(3).

The Motion to Reconsider or Alternatively Certify for Appeal (#33) is **DENIED** for the reasons discussed above.

Signed: May 10, 2017



Max O. Cogburn Jr
United States District Judge